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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/007,445 | 11/05/2001 | Thomas H. Gilman | 30056/37692 | 3356 |

4743 7590 09/26/2003

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EXAMINER

LEWIS, KIM M

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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3761

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/007,445

Applicant(s)

GILMAN, THOMAS H.

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/25/02, 3/21/02, 7/23/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-9 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed 2/25/02, 3/21/02 and 7/23/03 have been received and made of record in the application file wrapper. Note the acknowledged PTO-1449 forms enclosed herewith.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "29" as recited on page 8, line 19. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
3. The drawings are objected to because the description of reference character "16" in Fig. 1 should not be present in the drawing since the description appears in the specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities:

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Page 4, line 28, the recitation "...a **somewhat** schematic cross-sectional view..." **(emphasis added by the examiner)** is confusing. Either the view is a cross-sectional view or it isn't. Appropriate correction is required.

Claim Objections

5. Claims 1 and 8 are objected to because of the following informalities:

Claim 1, line 10, after "permeable" insert --,--;

Claim 1, line 12, delete "thereto"; and

Claim 8, line 2, "opening" should read --openings--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As regards claim 7, lines 1-2, "said flexible foraminous layer lacks proper antecedent basis.

As regards claim 9, in line 1, "said openings" lack proper antecedent basis. Also, in lines 1-2, "said flexible foraminous layer" lacks proper antecedent basis.

The remaining claim is necessarily rejected as being dependent upon a rejected base claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,556,375 ("Ewall") in view of U.S. Patent Nos. 3,903,232 (Wood et al.) and U.S. Patent 5,086,764 ("Gilman")

As regards claims 1, 4 and 5, Ewall discloses a wound dressing having a fenestrated base layer that substantially reads on the instant claim. More specifically, Ewall discloses a base layer (10) having a central fenestration (11), a pad (12) positioned above the fenestration, and a cover sheet (13). Ewall also discloses that the base layer is an elastomeric layer that is gas permeable and liquid impermeable (col. 4,

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lines 6-22), that the pad can be constructed from absorbent materials such as gauze, cotton, absorbent sponges, etc. (col. 4, lines 23-30), and that the coversheet is constructed from polyurethane film, which is inherently elastomeric (col. 4, lines 40-53 and lines 61-64). Ewall fails to disclose that the base layer is a film layer and that the pad is a soft, hydrophilic polymeric foam layer.

As regards the base layer, Gilman discloses an absorbent dressing comprising an elastomeric film layer constructed from the same material as the base layer of the instant invention. Gilman further discloses that the base layer is gas permeable, liquid impermeable and resistant to the passage of bacteria.

In view of Gilman, it would have been obvious to one having ordinary skill in the art to substitute the base layer of Ewall for film base layer of Gilman in order to resist the passage of bacteria. Such a substitution requires only an exchange of equivalent parts.

As to the foam layer, Woods et al. teach it is conventional to provide soft hydrophilic foam layers in the form of sponges for body usage in medical applications (col. 1, lines 52-64). It would have been obvious to one having ordinary skill in the art to substitute the absorbent sponge of Ewall for the soft, hydrophilic polymeric foam sponge disclosed in Woods et al. since the substitution of one sponge for another sponge requires only routine skill in the art. Additionally, the examiner contends that both sponges perform equally well.

As regards claim 2, note claim 6 of Ewall, which discloses that the cover sheet is adhered to the base sheet.

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11. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewall in view of Woods et al. and Gilman as applied to claim 1 above, and further in view of U.S. Patent No. 5,902,260 ("Gilman et al.").

As regards claims 6-9, Ewall, Woods et al. and Gilman fail to teach a flexible and stretchable foraminous layer that extends over the surface of a backing layer opposite the foam layer. However, Gilman et al. teach a foraminous backing layer of stretchable and flexible material having a multiplicity of rectangular-shaped openings (abstract). The foraminous layer is constructed from soft foam (col. 3, lines 45-53) and is secured to a film layer for the purpose of adding support to the film layer while still allowing the film layer to be viewed.

In view of Gilman et al., it would have been obvious to one having ordinary skill in the art to provide the backing layer of the modified dressing of Ewall, Woods et al. and Gilman with a foraminous layer of stretchable and flexible material having a multiplicity of rectangular-shaped openings secured for the purpose of adding support to the backing layer while still allowing the backing layer to be viewed.

Allowable Subject Matter

12. Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

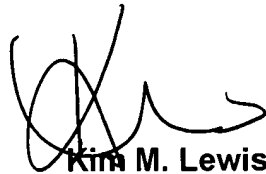
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is

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703.308.1191. The examiner can normally be reached on Mondays and Tuesdays from 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703.308.1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703.305.3590 for regular communications and 703.305.3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.



Kim M. Lewis
Primary Examiner
Art Unit 3761

kml
September 1, 2003